



UNITED STATES PATENT AND TRADEMARK OFFICE

OCT 20 2009

Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

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In Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,254,556

**DECISION ON APPLICATIONS FOR PATENT TERM EXTENSION**

Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Applicant"), the owner of record of U.S. Patent No. 5,254,556 ("the '556 patent"), filed an application to extend the term of the '556 patent ("PTE application") under 35 U.S.C. § 156 in the United States Patent and Trademark Office ("USPTO"). Applicant is seeking extension based upon the premarket review under section 505 of the Federal Food Drug and Cosmetic Act of the human drug product known by the tradename Invega Sustenna™. Because the '556 patent is due to expire on October 27, 2009, Applicant has filed two applications for interim extension of the '556 patent, the first under 35 U.S.C. § 156(d)(5) and the second under 35 U.S.C. § 156(e)(2). The application for interim extension under § 156(d)(5) is **DENIED**, but the application for interim extension under § 156(e)(2) is **GRANTED** for a period of one year. To that end, an order granting interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of the '556 patent for a period of one year.

**FACTUAL BACKGROUND**

1. On October 19, 1993, the USPTO issued the '556 patent to Cornelius G.M. Janssen, Alfonsus G. Knaeps, Ludo E.J. Kennis, and Jan Vandenberg; it was originally assigned to Janssen Pharmaceutica, N.V. and is due to expire on October 27, 2009.
2. On December 19, 2006, the Food and Drug Administration ("FDA") approved New Drug Application ("NDA") No. 21-999, thereby granting permission for the commercial marketing or use of Invega®, which is the brand name for paliperidone.
3. On July 7, 2009, Applicant filed an application for an interim patent term extension in accordance with the provisions of § 156(d)(5) based on the then continuing regulatory review of NDA No. 22-264 for Invega Sustenna™, which is the brand name for paliperidone palmitate, by the FDA.
4. On July 31, 2009, the FDA approved NDA No. 22-264, thereby granting permission for the commercial marketing or use of Invega Sustenna™.
5. On August 6, 2009, Applicant filed a PTE application under § 156 to extend the term of the '556 patent based on the FDA regulatory review period for NDA No. 22-264 of Invega Sustenna™ and an application for an interim patent term extension under § 156(e)(2).

## **DECISION**

### **I. Interim Extension Under 35 U.S.C. § 156(d)(5) is Denied**

Applicant filed an application for an interim patent term extension pursuant to the provisions of § 156(d)(5) on July 7, 2009. Section 156(d)(5) provides for an interim patent term extension of a patent claiming a product subject to regulatory review when the product is subject to on-going pre-market regulatory review by a regulating agency (e.g., FDA). See 35 U.S.C. § 156(d)(5). Here, the regulatory review period of the subject product concluded before the term of the '556 patent expired. Thus, the '556 patent is not eligible for an interim patent term extension under section 156(d)(5). Accordingly, the application for an interim extension based on continuing regulatory review by FDA of Invega Sustenna™ (NDA No. 22-264) is denied.

### **II. Interim Extension Under 35 U.S.C. § 156(e)(2) is Granted**

Applicant also filed an application for an interim patent term extension pursuant to the provisions of § 156(e)(2) on August 6, 2009. Section 156(e)(2) provides for an interim patent term extension while an applicant's PTE application is pending before the Office, if the Office determines that a patent is eligible for extension. See 35 U.S.C. § 156(e)(2); see also *Somerset Pharms., Inc. v. Dudas*, 500 F.3d 1344, 1346 (Fed. Cir. 2007) (confirming that the Director has no statutory authority to issue an interim extension once he denies a patent term extension application).

Section 156(a) sets forth several eligibility requirements for a patent term extension. See 35 U.S.C. § 156(a)(1) – (a)(5), (d)(1) & (e)(1). The sole requirement implicated in this patent term extension application is whether “the permission for the commercial marketing or use of the product . . . [to be] the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred.” 35 U.S.C. § 156(a)(5) (Hereinafter “First Commercial Marketing Provision”). More specifically, whether the '556 patent is eligible for patent term extension turns on whether the approval of Invega Sustenna™ meets the First Commercial Marketing Provision in light of the FDA's prior approval of Invega®. Under the current case law, which the USPTO notes is not settled, the USPTO preliminarily finds that the First Commercial Marketing Provision is met.

Section 156(f) defines the term “product” ultimately to mean “active ingredient . . . including any salt or ester of the active ingredient.” See 35 U.S.C. § 156(f). In *Photocure v. Dudas*, 622 F. Supp. 338, 347 (E.D. Va. 2008), the district court found that the term “active ingredient” means the ingredient physically present in the drug product upon administration. In reaching this definition, the district court followed *Glaxo Operations UK Ltd. v. Quigg*, 894 F.2d 392 (Fed. Cir. 1990), which it read to set forth a definition of “active ingredient” as used in the section 156(f)(2). *Id.* Under *Photocure*, it appears that the approval of Invega Sustenna™ complies with the requirements of the First Commercial Marketing Provision. Accordingly, the application for an interim extension under § 156(e)(2) is granted for a period of one year.

Although the USPTO presently finds that the '556 patent is eligible for a patent term extension under *Photocure*, the USPTO notes that the *Photocure* decision is currently on appeal to the Federal Circuit. See *Photocure v. Kappos*, Appeal No. 2009-

1393 (argued Sept. 8, 2009). Upon decision from the Federal Circuit, which is expected sometime in early 2010, the USPTO will, if necessary, reconsider its patent term extension eligibility determination in the present case. To that end, it is possible that the USPTO may seek further information from applicant about its initial determination of eligibility depending on the outcome of the Federal Circuit's decision.

### **CONCLUSION**

Applicant's request for an interim extension under 35 U.S.C. § 156(d)(5) is **DENIED**. Applicant's request for interim extension under 35 U.S.C. § 156(e)(2) is **GRANTED** for a period of one year.

Any correspondence with respect to this matter should be addressed as follows:

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Telephone inquiries related to this determination should be directed to Mary C. Till at (571) 272-7755.



Brian E. Hanlon  
Director  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Office of Regulatory Policy  
Food and Drug Administration  
10903 New Hampshire Ave., Bldg. 51, Rm 6222  
Silver Spring, MD 20993-0002

RE: INVEGA SUSTENNA™  
FDA Docket No.:

Attention: Beverly Friedman

# UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Ortho-McNeil-Janssen Pharmaceuticals, Inc. :  
Request for Patent Term Extension : ORDER GRANTING  
U.S. Patent No. 5,254,556 : INTERIM EXTENSION

Ortho-McNeil-Janssen Pharmaceuticals, Inc., the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 5,254,556, filed an application for patent term extension under 35 U.S.C. § 156 on August 6, 2009. The original term of the patent is due to expire on October 27, 2009. The patent claims paliperidone palmitate, labeled as the active ingredient in the human drug product Invega Sustenna™, which was approved by the Food and Drug Administration for commercial marketing or use on July 31, 2009. An extension of 1,449 days is requested.

The initial USPTO review of the application to date indicates that the subject patent is eligible for extension under 35 U.S.C. § 156. Because the original term of the patent would expire before a certificate of patent term extension can be issued or denied, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 5,254,556 is granted for a period of one year from the original expiration date of the patent, i.e., until October 27, 2010.

10/7/09  
Date

  
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David J. Kappos  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office